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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,451	07/31/2001	Louis Schofield	017227/0174	8055

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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,451	SCHOFIELD ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/24/05 & 5/23/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 79-137* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-16,18,81-88,100,102-106,108-110,116-120,124 and 125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 4-8,17,79,80,89-99,101,107,111-115,121-123 and 126-137.

DETAILED ACTION

1. Applicant's amendments filed 1/24/05 and 5/23/05 are acknowledged and have been entered.

Claims 1-18 and 79-137 are pending.

2. Applicant is reminded of Applicant's election with traverse of Group I (claims 1-18 and 79-125), and species election of inducing an immune response, upregulation of the Th2 response, treatment or prophylaxis of the disease condition malaria using a GPI with the sequence EtN-P-[Ma2]Ma2Ma6Ma4Ga6Ino-Y in Applicant's response filed 10/17/03.

Claims 1-3, 9-16, 18, 81-88, 100, 102-106, 108-110, 116-120, 124 and 125 read on the elected species.

Accordingly, claims 4-8, 17, 79, 80, 89-99, 101, 107, 111-115, 121-123 (non-elected species of Group I) and claims 126-137 (non-elected groups II and III) stand withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 1-3, 9-16, 18, 81-88, 100, 102-106, 108-110, 116-120, 124 and 125 are currently being examined.

In view of Applicant's amendment filed 1/24/05, the following grounds of rejection remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3, 9-16, 18, 81-88, 100, 102-106, 108-110, 116-120, 124 and 125 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V.

Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the Applicant had possession at the time of invention of the claimed method of activating CD1-restricted Th (including CD1+ NK1.1+ T cells, Th2) cells comprising administration of a GPI derivative or equivalent thereof or complex thereof comprising or treatment or prophylaxis via administration of a GPI derivative or equivalent thereof or complex thereof

The instant claims encompass use of a derivative or equivalent of GPI to activate or induce Th cells in vitro or in vivo for treatment or for prophylaxis, including treatment or prophylaxis with GPI.

The specification discloses that GPIs consist of a conserved core glycan (Manα1-2Manα1-6Manα1-4GlcNH$_2$ linked to the 6 position of the myo-inositol ring of PI (sentence spanning pages 1 and 2). The specification further discloses other GPI that do not appear to comprise the conserved core glycan as defined above (pages 3-7), for example, EtN-P-Manα2-Manα6-M-Y (page 4 at line 2) or Manα2-Manα6-M-Y (page 7 at line 1). The specification discloses that "derivatives" or "equivalents" should be understood to include reference to fragments, parts, portions, chemical equivalents, mutants, homologs and analogs, and further that equivalents may not necessarily be derived from GPI but may share certain conformational similarities, or alternatively, chemical equivalents may be specifically designed to mimic certain physiochemical properties of GPI and may also include synthetic carbohydrates and peptide mimetics (page 15 at lines 2-11).

The specification as filed does not provide written description support for derivative or equivalent; the skilled artisan cannot envision all the contemplated substances by the label "derivative" or "equivalents" and therefore conception cannot be not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and along with a recitation of a function such as inducing Th cells. The derivative or equivalent itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

In addition, a definition by function does not suffice to define the genus because it is only an indication of what the property the peptide has, and if one extends the analysis in the instant case, what the peptide does (i.e., it induces a CD1-restricted Th cell response), rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06. It is only a definition of a useful result rather than a definition of what achieves that result. Many such species may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521,

222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. One of ordinary skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus as broadly claimed.

Applicant's arguments in the amendment filed 1/24/05 have been fully considered, but are not persuasive.

Applicant's arguments are of record in the said amendment on pages 18-19 at Section I.A., briefly, that (1): the specification discloses multiple formulas, which teach the essential portions of the molecules as well as identifies the areas available for modification and the extent of the modifications that can be made without disrupting the function of the molecule (Applicant cites pages 16-20 of the specification), and (2) the specification teaches several functional assays such as Examples 12-14 and 18.

It is the Examiner's position that the GPI disclosed in the specification do not all contain the same core mannan as enunciated above, and since the specification discloses that "derivatives" or "equivalents" should be understood to include reference to fragments, parts, portions, chemical equivalents, mutants, homologs and analogs, and further that equivalents may not necessarily be derived from GPI but may share certain conformational similarities, or alternatively, chemical equivalents may be specifically designed to mimic certain physiochemical properties of GPI and may also include synthetic carbohydrates and peptide mimetics, the structure of the GPI "derivatives" or "equivalents" is not envisioned by variant structures that are disclosed to be GPIs.

5. Claims 1-3, 9-16, 18, 81-88, 100, 102-106, 108-110, 116-120, 124 and 125 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention.

The specification does not disclose how to practice the instant method comprising activating Th cells comprising administering a T cell activating amount of GPI or derivative or equivalent thereof or complex comprising any of these, nor how to practice the claimed method of inducing in a mammal an immune response directed to GPI, nor how to practice the claimed method of treatment and/or prophylaxis of a mammalian disease condition, including said condition characterized by microorganism infection such as those recited in the instant claims, including malaria. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because: (1) the claims encompass treatment and/or prophylaxis of any mammalian disease or condition with GPI or GPI "derivatives" or "equivalents" of GPI that the

specification does not disclose how to make and/or use (claims 103-110,116-120, 124 and 125), (2) and/or a method of activating T helper cells or inducing an immune response in a mammal to an antigen comprising administering GPI "derivatives" or "equivalents" (claims 1-3, 9-16, 18 and 81-88) that are not substitution variants of the defined structures recited in instant claims 11 and 86).

The specification discloses that GPIs consist of a conserved core glycan (Manα1-2Manα1-6Manα1-4GlcNH$_2$ linked to the 6 position of the myo-inositol ring of PI (sentence spanning pages 1 and 2). The specification further discloses other GPI that do not appear to comprise the conserved core glycan as defined above (pages 3-7), for example, EtN-P-Manα2-Manα6-M-Y (page 4 at line 2) or Manα2-Manα6-M-Y (page 7 at line 1). The specification discloses that "derivatives" or "equivalents" should be understood to include reference to fragments, parts, portions, chemical equivalents, mutants, homologs and analogs, and further that equivalents may not necessarily be derived from GPI but may share certain conformational similarities, or alternatively, chemical equivalents may be specifically designed to mimic certain physiochemical properties of GPI and may also include synthetic carbohydrates and peptide mimetics (page 15 at lines 2-11).

The specification does not disclose any working examples of treatment or prophylaxis of any condition or disease *in vivo*, including in a mammal, comprising administration of GPI, derivatives or equivalents.

Evidentiary reference Schofield et al (Nature 2002, 418: 785-789) teaches that anti-GPI immunization prevents the development of pulmonary edema and acidosis as well as cerebral malaria in 75% of P. *berghei* infection in mice, but vaccination did not prevent late-end stage infection characterized by overwhelming parasitemia associated with profound hemolytic anemia in mice and subsequent death (especially column one on page 788). Schofield et al further teach that the issue of whether GPI is a target of clinical immunity remains to be determined, that in contrast to acquired clinical immunity, anti-parasite immunity takes many more years to develop and is easily lost, reflecting the problems of antigenic diversity, antigenic variation, redundancy in invasion pathways, immune evasion strategies and genetic restriction in the immune response to parasite antigens (especially page 788 at column 2). Evidentiary reference Schofield et al teaches that although P. *berghei* is the best available model for certain aspects of lethal pathogenesis, it is not considered to model adequately these aspects of human malaria anemia, *i.e.*, erythropoietic suppression (especially column 1 on page 788). Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

Applicant's arguments in the amendment filed 1/24/05 have been fully considered, but are not persuasive.

Applicant's position is of record on pages 19-20 at section I.B., briefly, that: (1) the skilled artisan can easily identify functional derivatives or equivalents for use in treatment or prevention of mammalian disease by using the formulas and functional assays taught in the specification, *e.g.*, the specification in Example 22 describes the use of a mouse model to determine GPI's effectiveness with regards to malaria sporozoites, (2) the Schofield et al evidentiary reference is irrelevant for the present claims because the present invention claims that GPI may be used to activate Th cells, i.e., invoke an antibody response, and The said reference clearly supports GPI activation of Th cells because GPI was shown to prevent pulmonary edema, acidosis and cerebral malaria through the GPI-induced production of antibodies (p. 787 Fig. 2 and p. 788 col. 1), and so the reference supports that there is no undue experimentation required to use GPI derivative or equivalents to activate Th cells.

It is the Examiner's position that: (1) although the skilled artisan can identify substitution variants of the specific formulas recited in instant claims 11 and 86, for example, the scope of the limitation "equivalents" or "derivative" encompasses homologs, analogs and molecules not related to or derived form those specific formulas, the breadth of the claims is not limited to these substitution variants, and the GPIs disclosed in the specification do not all possess the same core mannan structure or a specific general formula(e), and (2) although Schofield et al teach activation of Th cells to induce an antibody response in mice infected with P. *berghei*, the breadth of the claims is not limited to induction of antibody response in infected mice, but to treatment or prophylaxis *of any mammalian disease condition,* including characterized by microorganism infection (claim 109 for example) or not (claim 103 for example), in any mammal, and Schofield et al teach that the issue of whether GPI is a target of clinical immunity in other than the experimental P. *berghei* infected mouse system remains to be determined as enunciated supra.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. For the purpose of prior art rejections, the filing date of the instant claims 11-13, 86-88, and 116-118 is deemed to be the filing date of the PCT application PCT/AU99/00929, i.e. 10/27/99, as the foreign priority application AU PP 6758 does not support the claimed limitations of the instant application. There is no disclosure of the chemical species recited in the said instant claims 11-13, 86-88 and 116-118 in the said foreign priority application.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 9-18, 81-88, 100, 102-106, 108, 109, 116-120, 124 and 125 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schofield et al (J. Exp. Med. 1/93 177: 145-153) as evidenced by Nagata et al (Eur. J. Immunol. 1993 23: 1193-1196).

Schofield et al teach administration of P. *falciparum* GPI or analogues, including containing diacylglycerol, or from T. *brucei* (comprising phosphatidylcholine) *in vivo* for production of anti-GPI antibodies in the treatment of malaria (especially page 152, page 149, page 150). Schofield et al teach cerebral malaria is a type of malaria to be treated by administering GPI (especially page 152, column 2).

Evidentiary reference Nagata et al teaches that Th2 cells secrete IL-4, IL-5 and IL-6 and provide the major help for antibody production of T cells (especially first paragraph on page 1193).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. When a claim recites using an old composition or structure (e.g., GPI or analogues) and the use is directed to a result or property of that composition or structure (activating $CD4^+$ $NK1.1^+$ Th2 cells following administration for antibody production against GPI in treatment of malaria) then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. v. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. v IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

Applicant's arguments in the amendment filed 1/24/05 have been fully considered, but are not persuasive.

Applicant's position is of record on page 20 at section III, briefly that: (1) the Schofield et al reference teaches that GPI is a toxin of malaria parasites and acts as a T-independent antigen, eliciting responses from B-cells without T cell help, but that the present application teaches administration of GPI activates Th cells which then elicits the antibody response useful for treatment and prevention of mammalian diseases, and (2) the said reference teaches away from administering GPI to treat mammalian diseases because all of the mice injected with the GPI died, and so a skilled artisan would not administer GPI to activate T cells.

It is the Examiner's position that: (1) it is an inherent property of art method that administration of GPI results in GPI binding to CD1d and the resulting complexes activating NK1.1 Th cells (and as further evidenced by the Schofield et al reference (1999) cited in the following rejection which teaches that IgG production was regulated through IL-4-producing CD4+ NK1.1 Th cells that recognize GPI/CD1d complexes), and the instant claims recite activation of Th cells by administering GPI, and (2) the instant rejection is not an obviousness-type rejection, but rather anticipation. In addition, the art reference teaches that the animals showed signs of transient pyrexia, but did not die as a result as injection of purified malarial GPI in saline (especially page 151 at column 1 at the full paragraph).

10. Claims 11-13, 86-88 and 116-118 stand rejected under 35 U.S.C. 102(a) as being anticipated by Schofield et al (Science 283: 225-229, 1/8/99) as evidenced by van Joost et al (J. Amer. Acad. Dermatol. 27: 922-8, 1992) and Paul (Fundamental Immunol. 2nd Ed., 1989, New York, Raven Press, page 405).

Schofield et al teach COOH-terminal GPIs from P. *falciparum* and T. *brucei* that have the same structure as the elected species, as well as GPIs from other sources such as parasitic protozoa (especially Figure 1 and page 228). Schofield et al further teach CD1-restricted recognition of GPI moieties, including those linked to diacylglycerol or alkylacylglycerol (especially paragraph 1, column 1 on page 227), by $CD4^+$ NK1.1 Th cells, and production of high levels of IL-4 (involved in Th2 type responses). Schofield et al teach a method of activating or inducing T helper cells *in vivo* comprising administering GPI or a derivative or equivalent because Schofield et al teach administration of malaria to mice, and teach the use of GPI in vaccines to treat various pathogens such as malaria.

Evidentiary reference van Joost et al teaches that Th2 lymphocytes produce IL-4 (especially page 922), and evidentiary reference Paul teaches that Th2 cells produce IL-4 and that IL-4 induces IgG1 and IgE production from B cells.

Applicant's arguments in the amendment filed 1/24/05 have been fully considered, but are not persuasive.

Applicant's position is of record on page 21 of the said amendment, briefly that the 1998 date allegedly is the proper priority date for the claims under rejection because the specific GPI molecules covered by the present claims were taught in the provisional application's description of GPI genus as a whole.

It is the Examiner's position that there is no priority claim to a provisional application, but that the foreign priority document AU PP 6758 does not disclose the chemical species recited in the instant claims under rejection. It is the Examiner's further position that disclosure of the genus of "GPI" does not provide support for the subgenus' and species recited in the instant claims.

11. Claims 11, 13, 86, 88, 116 and 118 stand rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/52547 (10/21/99).

WO 99/52547 teaches treatment of malaria or other parasitic infections comprising administering GPI to induce a $CD4^+$ T cell response, including also inducing B cell activation through a T cell response, i.e., activation of $CD4^+$ Th2 cells (especially page 3 at lines 9-21, pages 9-10, 12, 18, 19 and claims). WO 99/52547 teaches Plasmodium genus and species (especially pages 3, 10, 11 and 12 and claims). WO 99/52547 further teaches phospholipids such as phosphatidylinositol, phosphatidylethanolamine and phosphatidylglycerol (page 21).

With regard to inclusion of claims 11, 86 and 116 in this rejection, claims 11, 86 and 116, recite "or derivatives or equivalents thereof".

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. When a claim recites using an old composition or structure (e.g., GPI) and the use is directed to a result or property of that composition or structure (activating $CD4^+$ $NK1.1^+$ Th cells following administration) then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. v. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. v IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

Applicant's arguments in the amendment filed 1/24/05 have been fully considered, but are not persuasive.

Applicant's position is of record on page 21 of the said amendment, briefly that the 1998 date allegedly is the proper priority date for the claims under rejection because the specific GPI molecules covered by the present claims were taught in the provisional application's description of GPI genus as a whole.

It is the Examiner's position that there is no priority claim to a provisional application, but that the foreign priority document AU PP 6758 does not disclose the chemical species recited in the instant claims under rejection. It is the Examiner's further position that disclosure of the genus of "GPI" does not provide support for the subgenus' and species recited in the instant claims.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 11-13, 86-88, 116-118 stand rejected under 35 U.S.C. 103(a) as being obvious over WO 99/52547 (10/21/99) in view of Tachado et al (PNAS USA 94: 4022-4027, 4/97) and Joyce et al (Science 279: 3/6/98, pages 1541-1543).

WO 99/52547 teaches treatment of malaria or other parasitic infections comprising administering CD1-binding GPI to induce a $CD4^+$ T cell response, including also inducing B cell activation through a T cell response, i.e., activation of $CD4^+$ Th2 cells (especially page 3 at lines 9-21, pages 9-10, 12, 18, 19 and claims). WO 99/52547 teaches Plasmodium genus and species (especially pages 3, 10, 11 and 12 and claims). WO 99/52547 further teaches phospholipids such as phosphatidylinositol, phosphatidylethanolamine and phosphatidylglycerol (page 21). With inclusion of claims 11, 86 and 116 in this rejection, claims 11, 86 and 116, recite "or derivatives or equivalents thereof".

WO 99/52547 does not teach the treatment of malaria or other parasitic infections comprising a GPI that comprises diacylglycerol.

Tachado et al teach GPI from P. *falciparum* malarial parasite that comprises diacylglycerol.

Joyce et al teach that GPI is a major natural ligand of CD1d1 that controls the function of $NK1.1^+$ T cells.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the GPI taught by Tachado et al or by Joyce et al in place of the GPI taught by WO 99/52547 in the method taught by WO 99/52547.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat malaria.

Applicant's arguments in the amendment filed 1/24/05 have been fully considered, but are not persuasive.

Applicant's position is of record on page 21 of the said amendment, briefly that the 1998 date allegedly is the proper priority date for the claims under rejection because the specific GPI molecules covered by the present claims were taught in the provisional application's description of GPI genus as a whole.

It is the Examiner's position that there is no priority claim to a provisional application, but that the foreign priority document AU PP 6758 does not disclose the chemical species recited in the instant claims under rejection. It is the Examiner's further position that disclosure of the genus of "GPI" does not provide support for the subgenus' and species recited in the instant claims.

14. No claim is allowed.

15. It is noted that in Applicant's amendment filed 1/24/05, instant claim 100 has an incorrect status identifier, i.e., (Withdrawn), as the claim is under examination.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
July 12, 2005

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600